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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/935,487	08/23/2001	Robert F. Rioux	BSCU-128/00US 027060-2694	1401
58249 7590 12/01/2009 COOLEY GODWARD KRONISH LLP ATTN: Patent Group Suite 1100 777 - 6th Street, NW WASHINGTON, DC 20001			EXAMINER PELLEGRINO, BRIAN E	
			ART UNIT 3738	PAPER NUMBER
			MAIL DATE 12/01/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/935,487	Applicant(s) RIOUX ET AL.	
	Examiner Brian E. Pellegrino	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 September 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,7,8,17-20,22 and 24-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,7,8,17-20,22 and 24-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 January 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

In response to applicant's argument that Beyar does not explicitly state the coil segment is extended by "winding" the coil and being compressible by "releasing" the coil, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Applicant's arguments with respect to claim 1 have been considered but are moot in view of the new ground(s) of rejection. The coil of Beyar has hooks on its ends for grasping with a delivery tool. Yachia also teaches hooks on the ends of a coil and that it permits the extension and compression of a coil. Therefore, the coil of Beyar is fully capable of being manipulated by a tool to wind it to extend it and release it to compress it as taught by Yachia.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the distal and proximal portions have more than one hook must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet,

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even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 29 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The new limitation that each of the distal and proximal portions can include more than one hook is new matter. It is noted that Applicant describes (paragraph 35) as best understood (and shown) that there is two hooks possibly on the coil. While it may be understood that different locations

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are possible, it did not state more than two hooks. Thus, it is suggested to not claim more than two hooks on the coil. Applicant is also advised to make that clear in claim 1. It is understood that two hooks can be claimed, but in different locations as in claim 1, but not more than 2 is permissible, so this language of claim 1 is suggested to be clarified.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-4,17-20,22,24-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beyar et al. (5372600) in view of Yachia et al. (5246445) and Goicoechea (6010530). Beyar et al. disclose a stent for use within a body lumen, col. 3, lines 16-18. It can be seen (Fig. 3) that the stent **17** is a unitarily formed coil segment defining a lumen there through and includes distal, middle and proximal portions. Beyar et al. also discloses the distance between a coil winding of a stent placed in a vessel is at least about 0.5mm, col. 7, lines 5-7. Beyar discloses the coil segment being extendable lengthwise from a first length to an extended length and being compressible lengthwise from the extended length, col. 4, lines 18-38. It can also be seen (Fig. 6) there is at least one hook **16** on proximal and distal portions to permit connection to a delivery system **12**. Beyar additionally states the structures for attachment can be hooks at both the proximal and distal ends of the coil body for connection to a delivery system, col. 7, lines 8-17. Beyar et al. does disclose (col. 7, lines 18,19) varying diameter for the stent but does not explicitly state the stent having each of the distal and proximal portions including a diameter greater than a diameter of the middle portion. Beyar also discloses (col. 6, line 60) coating layers

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of silicone can be placed on the wire, but does not explicitly state it is placed such that the polymer material encapsulates the coil segment and disposed between the spaced windings of the wound element to form an imperforate flexible webbing. Yachia et al. teach (Fig. 1a) a stent in the form of a coil segment with a middle portion and proximal and distal portions **2** and as seen the middle portion has a diameter less than the proximal and distal portions which have a greater diameter for anchoring in a vessel, col. 5, lines 7-9. Yachia also teaches the use of hooks on the ends to control delivery of the coil such that it can be extended by winding and released to compress, col. 5, lines 16,17, col. 6, lines 13-31. Goicoechea teaches (Figs. 1,2) a stent **11** which has been encapsulated by a flexible polymer material **12** that encapsulates the coil segment and has an outer **14** and inner layer **15**. It would have been obvious to one of ordinary skill in the art to incorporate larger diameter distal and proximal portions as taught by Yachia et al. with the coil of Beyar et al. such that it enables the stent to be better anchored when used in a vessel such as the prostatic urethra. Additionally, it would have been further obvious to one of ordinary skill in the art to incorporate a flexible polymer webbing that encapsulates the stent as taught by Goicoechea with the coil of Beyar et al. as modified with Yachia such that it holds a radiopaque material for enhance visibility, see Goicoechea, col. 4, lines 66,67. Regarding claims 2,3,25,26 Beyar discloses the wire is biocompatible and can be stainless steel, col. 6, lines 52-60. With respect to claim 4,27 Beyar additionally disclose (col. 6, lines 64-66) the wire cross-section area is in the range of $0.0079 - 0.0071\text{mm}^2$. With respect to claims 20,22, Beyar discloses the stent is placed in the prostatic urethra before the sphincter, col. 7, lines 62-65 and thus has sufficient strength to maintain an open passageway. Regarding claim 28, Beyar discloses the separation between coil windings to fall within the claimed range of about 0.5-10mm, col. 7, lines 5-7.

Claims 7,8,30,31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beyar et al. '600 in view of Yachia et al. '445 and Goicoechea '530 as applied to claim 1 and further in view of Hachtman et al. (5645559). Beyar et al. in view of Yachia and Goicoechea is explained supra. However, Beyar as modified with Yachia and Goicoechea do not disclose the silicone is a *low durometer* silicone within the range of 0-60D. Hachtman et al. teach that a silicone layer is placed on the stent to provide a barrier that prevents the growth of tissue through the stent and to support the flow of fluid through the lumen, col. 2, lines 14-18. Hachtman et al. also teach that low durometer silicone, such as 30D is placed on a stent, col. 4, lines 49-52. It would have been obvious to one of ordinary skill in the art to use a 30D silicone as taught by Hachtman et al. for the silicone on Beyar et al. wire stent modified with Yachia and Goicoechea such that fluid flow is maintained through the lumen of the device while preventing tissue ingrowth.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M- F (9am-5:30pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TC 3700
/Brian E Pellegrino/
Primary Examiner, Art Unit 3738